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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,305	04/08/2004	William Andrew Wilson	P06296US02 - PHI 1443	7443
27142	7590	07/06/2006	EXAMINER	
MCKEE, VOORHEES & SEASE, P.L.C. ATTN: PIONEER HI-BRED 801 GRAND AVENUE, SUITE 3200 DES MOINES, IA 50309-2721			IBRAHIM, MEDINA AHMED	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

10/820,305

Applicant(s)

WILSON ET AL.

Examiner

Medina A. Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13, 14 and 20 is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-19 and 21-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Rule 105

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/11/06 has been entered.

The terminal disclaimer filed on 01/05/06 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US pat 6, 784, 349 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claims 1-34 are pending and are examined.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-12, 23, 25-28, and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is indefinite for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: repeating steps

REQUEST FOR INFORMATION UNDER 37 CFR § 1.105

1. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application, 10/820, 305.

2. This request is being made for the following reasons:

Applicant is claiming seed/plant comprising at least a set of chromosomes of inbred line PH8CW; hybrid maize seed/plant produced by crossing maize plants of inbred line PH8CW with plants of another different maize inbred line and plant comprising at least 95% of the alleles of inbred line PH8CW. However, the specification is silent about what starting materials and methods were used to produce line PH8CW. The requested information is required to make a meaningful and complete search of the prior art.

3. In response to this requirement, please provide answers to each of the following interrogatories eliciting factual information:

(i) What were (are) the original parental corn lines used to produce inbred line PH8CW. Please supply all designations/denominations used for the original parent lines and any corn variety produced using said original parental lines. Please supply information pertaining to the lineage of the original parental lines back to any publicly available varieties.

(ii) What method and method steps were used to produce corn line PH8CW?

(iii) At or before the time of filing of the instant application or any provisional application to which benefit is claimed, had any of said parental corn lines or progeny

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therefrom been disclosed or made publicly available? If so, under what designations/denomination and under what conditions were said parent corn lines or progeny disclosed or made publicly available and from when to when?

(iv) At or before the time of filing of the instant application or any provisional application to which benefit is claimed, were any other corn lines produced by said method using said original parental corn lines, and if so, had said produced corn lines been publicly available or sold? If so, under what designations/denomination and under what conditions were said other corn lines disclosed or made publicly available and from when to when?

4. If Applicant views any or all of the above requested information as a Trade Secret, then Applicant should follow the guidance of MPEP § 724.02 when submitting the requested information.

5. In responding to those requirements that require copies of documents, where the document is a bound text or a single article over 50 pages, the requirement may be met by providing copies of those pages that provide the particular subject matter indicated in the requirement, or where such subject matter is not indicated, the subject matter found in applicant's disclosure. Please point to the specific sections where the relevant information can be found.

6. The fee and certification requirements of 37 CFR 1.97 are waived for those documents submitted in reply to this requirement. This waiver extends only to those documents within the scope of this requirement under 37 CFR 1.105 that are included in the applicant's first complete communication responding to this requirement. Any

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(c) and (d) for at least three or more times in order to produce progeny plants having the desired trait and comprising at least 95% of the alleles of inbred line PH8CW.

Claim 12 is indefinite because it is unclear if a plant having the desired trait and comprises at least 95% of the alleles of inbred line PH8CW is produced from the method of claim 11, since the method of claim 11 lacks essential method steps.

Claims 23-28 improperly depend from claim 13. The claims do not incorporate all elements of the parent claim. The plant of parent claim 13, PH8CW, does not contain a single locus conversion or any of the locus conferring traits as listed in claims 26-28. For example, claims 26-27 recite gene conferring male sterility. However, the parent plant is male fertile. See pages 22 of the specification (line 38, where the plant is characterized as having pollen shed rated as 5.7 (on a scale from zero being male sterile to 9 being heavy pollen shed). The plant of parent claim 13, PH8CW, does not contain a transgene, allele or locus. Therefore, claims 23- 28 do not incorporate all elements of the claim from which it depends.

Claim 32 is indefinite in the recitation of "using" without any active method steps. Dependent claims 33 and 34 are included in the rejection.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 15-19, 21-26, 29-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a seed comprising at least one set of chromosomes of maize inbred line PH8CW, a maize plant produced from said seed; an F1 hybrid seed produced by crossing a plant of the maize inbred line PH8CW with a different maize plant, wherein said F1 hybrid seed comprises at least one set of chromosomes of the maize inbred line PH8CW, and maize plant produced by growing said F1 hybrid seed. The claims are also drawn to a process of introducing a desired trait into maize inbred line PH8CW through steps (a) to (e), and plant produced from said process, wherein the plant comprises at least 95% of the alleles of inbred line PH8CW at the SSR loci listed in Table 4. The claims are further drawn to maize plant/seed further comprising a transgene/allele/single gene conversion. In contrast, Applicant describes inbred maize line PH8CW having specific characteristics that distinguish the line from other corn lines. Applicant also describes F1 hybrid seed/plants of PH8CW for performance comparison with known hybrids. However, Applicant has neither described a method of reproducing the disclosed F1 hybrid nor does Applicant indicate that the seed of said F1 hybrids of the inbred PH8CW have been deposited and are publicly available.

The Federal Circuit court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or} chemical name, of the

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supplemental replies subsequent to the first communication responding to this requirement and any information disclosures beyond the scope of this requirement under 37 CFR 1.105 are subject to the fee and certification requirements of 37 CFR 1.97.

7. The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

8. This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.


ANNE MARIE GRUNBERG
SUPERVISORY PATENT EXAMINER

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claimed subject matter sufficient to distinguish it from other material". *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). The court also stated "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of is not a description of that material". *Id.* Further, the court stated that to adequately describe a claimed genus, Applicant must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of members of the genus". *Id.*

Applicant has not described the morphological and/or genotypic characteristics that would distinguish a seed comprising at least one set of chromosomes of inbred PH8CW and for all hybrid corn plants and seeds produced by crossing the inbred maize line PH8CW with another unidentified maize plant. No specific morphological or genotypic characteristics that distinguish the claimed seed/plant and hybrids from other corn plants and seeds are described. The only description recited in the claims is that the seed/plant and hybrids comprise at least one set of chromosomes from inbred PH8CW. This at least one set of chromosomes are unknown because inbred PH8CW is not genotypically described. In addition, this description is insufficient to provide a distinguishing characteristics, given that all hybrids comprise at least one set of chromosomes from one of its parents.

Furthermore, variation is expected in the complete genomes and phenotypes of the different hybrid species of the genus, since each hybrid has one non-PH8CW parent that is not shared with the other hybrids. Each of the hybrids would inherit a different set of alleles from the non-PH8CW inbred parent. As a result, the complete genomic

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structure of each hybrid, and therefore the morphological and physiological characteristics expressed by each hybrid, would differ. The phenotypic characteristics of the hybrid depends on how each allelic product interacts with the corresponding allelic product inherited from the other genome, as well as how each gene product interacts with the other gene products in the genome.

Given that a claimed seed/plant and F1 hybrid seed/ plant comprise a set of alleles inherited from each parent and these two sets of alleles interact in a variety of ways to determine the hybrids morphological and physiological traits, one cannot correlate the alleles inherited from PH8CW alone, with the phenotype of the progeny seed/plant or hybrid. Therefore, the description of parent inbred line PH8CW and the deposit of PH8CW seed are insufficient to provide adequate written description for seed/plant comprising at least one set of chromosomes of inbred PH8CW or for all hybrid progeny that may be produced by crossing PH8CW plants with any second, distinct corn plants.

Tables 3A-3F describe the performance comparison of hybrids of PH8CW with prior art hybrids. However, these hybrids are not representative species, given the large genus claimed and the variation expected among the hybrids. Table 4 of the specification lists SSRs profiles of inbred PH8CW. Applicant asserts that these SSRs can be used to identify all F1 hybrids having inbred PH8CW as one of their parents. However, while all claimed F1 hybrids would inherit the SSR marker profile of PH8CW, they will not inherit the same genetic markers from the second parents as different parents will have different markers. The SSRs of the non-PH8CW parents are not

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described. In addition, the instant specification does not describe the sequences of the primers that were used to produce these SSRs.

Claims 11-12, 19, 21 are further rejected because the SSR loci listed in Table 4 are not structurally or functionally described. The SSR are described by name only, and not by trait or by structure such as sequence.

Claims 23-25, drawn to a maize plant of inbred PH8CW further defined as having a genome with single locus conversion, are rejected because the claims do not place any limitation on the trait conferred or affected by the single locus conversion. The claims also broadly encompass single loci that have not been discovered or isolated.

Claim 26 is rejected. The specification indicates a single locus conversion of PH8CW occurs when DNA sequences are introduced into the plant by traditional breeding techniques such as backcrossing (page 30, 1st full paragraph). However, the specification provides no description of any plant produced by classical breeding methods such as backcrossing or recurrent selection. No other maize plant ("donor parent") exhibiting a single desired trait for use in backcross breeding has actually been disclosed and described, and no resulting progeny from such a cross has actually been disclosed or described. Furthermore, the individual genes conferring the desired traits have not been characterized, and the genes for several of the contemplated traits, i.e. "improved nutritional quality" and "yield stability" as claimed in claim 26 have not been isolated. In fact, the genes conferring such traits are thought to be quantitative in nature, i.e. governed by multiple genes, often occurring on different chromosomes, which additively contribute to the desired effect.

Claims 29-32 are included in the rejection because the claims read on a method for crossing PH8CW with a multitude of non-exemplified breeding partners which have not been characterized either morphologically or genetically. Only PH8CW has been morphologically described in the specification, as possessing a particular combination of traits as set forth in Table 1. PH8CW has not been described with regard to its genetic complement, i.e. the particular collection of genes that confer all of the traits it exhibits.

Claims 33-34 are included in the rejection because the claims require the use of a multitude of non-exemplified molecular markers. The instant specification does not characterize or described even one maize molecular marker, with regard to sequence, length or source. Thus, the claim reads on a method of using inadequately described products, rendering the method of using such products similarly inadequately described.

Given the vast number of hybrids encompassed by the claims; the substantial variation in phenotypes expected among these hybrids; and the vast number of unidentified non-PH8CW involved in the breeding, the disclosure of a single hybrid of the inbred PH8CW will not provide adequate written description for all F1 hybrids from inbred PH8CW.

Accordingly, the claimed invention lacks adequate written description as required under the current written description guidelines (See Written Description Requirement published in Federal Registry/Vol.66, No. 4/Friday, January 5, 2001/Notices; P. 1099-1111).

Claim Rejections - 35 USC § 102/103

Claims 1-10, 15-18, 22, and 26-34 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carlone, Jr.; Mario Rosario (US Pat. 6, 180, 857).

The claims are drawn to seed comprising at least one set of chromosomes of inbred maize PH8CW, plant produced from said seed; hybrid corn plant/seed produced by crossing the inbred line PH8CW with plants of another inbred line, and a method for using said hybrid plants/seeds to produce further subsequent generation plants/seed. The claims are also drawn to various breeding techniques used to generate hybrid plants/seeds.

Carlone, Jr. teaches hybrid maize designated 33P66, seed and plant of said hybrid; maize plant derived from said hybrid, and a method of producing hybrid seed/plant comprising in its material a transgene that confers male sterility or resistance to herbicide or diseases. The cited reference also teaches the development of hybrid maize variety by using maize plant breeding programs involving selection of plants from various germoplasm pools, selfing or crossing of the selected plants to produce inbred and hybrid lines. The cited reference also teaches backcrossing and pedigree breeding, genetic marker enhanced selection and transformation methods to transfer a desirable trait between plants (see at least columns 1-5). The seed and plants of the instant claims and those of the prior art share morphological and agronomic characteristics such as dark green leaf ; leaf sheath pubescence of 1.0 (none); red anther; pink silk; slightly curved row; average ear taper; buff dry husk; upright ear position; yellow

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aleurone; staygreen of 5; resistance to common rust (*puccinia sorghi*); resistance to gray leaf spot; resistance to northern/southern leaf blight resistance; resistance to diplodia ear rot resistance to fusarium ear and kernel rot; (see columns 13-16). Given these similar characteristics, the claimed seed/plant and those of the prior art are indistinguishable. The Examiner does not have sufficient facts to determine whether the corn plant and seeds are inherently the same and cannot conclude that the claimed subject matter would have been obvious since it cannot be determined whether the corn plants differ. Where the prior art product seems to be identical, except that the prior art is silent to a characteristic or property claimed, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. See *In re Best* 195 USPQ 430, 433 (CCPA 1977).

Remarks

Claims 13-14 and 20 are free of the prior art of record.

Claims 13-14, 20 are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

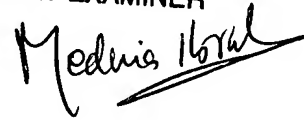
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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6/19/06

Mai

MEDINA A. IBRAHIM
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Medina Ibrahim", written over a horizontal line.